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TECH CENTER 1600/2900

In re Application of:

D'AMATO

Serial No. 09/545,139

Filed: APRIL 7, 2000

For: METHODS AND COMPOSITIONS FOR
INHIBITION OF ANGIOGENESIS WITH
EM-138

Art Unit: 1614

Examiner: J. Goldberg

RESPONSE TO FIRST OFFICE ACTION

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action issued May 11, 2001, a response to which is due by August 11, 2001, Applicants request reconsideration of the application in view of the following amendments and appended remarks.

CLEAN COPY OF AMENDMENTS: Pages 2-7.

REMARKS: Pages 8-9.

MARKED COPY OF CLAIMS: None Required.

06/06/2001 SMINASS1 00000053 09545139

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CERTIFICATION OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, DC 20231, on May 30, 2001.

Kimberly J. Prior
Kimberly J. Prior - Reg No. 41,483

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CLEAN COPY OF AMENDMENTS

In the Claims

Please cancel claims 2, 10-11, 13, and 15-22 without prejudice or disclaimer.

Please add new Claims 23-102.

- a' 9
23. (New) The method of Claim 1 wherein the eye condition is diabetic retinopathy.
- 10
24. (New) The method of Claim 1 wherein the eye condition is retinopathy of prematurity.
- 15
25. (New) The method of Claim 1 wherein the eye condition is corneal graft rejection.
26. (New) The method of Claim 1 wherein the eye condition is neovascular glaucoma.
27. (New) The method of Claim 1 wherein the eye condition is retrolental fibroplasias.
- 14
28. (New) The method of Claim 1 wherein the eye condition is epidemic keratoconjunctivitis.
- 15
29. (New) The method of Claim 1 wherein the eye condition is Vitamin A deficiency.
- 16
30. (New) The method of Claim 1 wherein the eye condition is contact lens overwear.
- 17
31. (New) The method of Claim 1 wherein the eye condition is atopic keratitis.
- 18
32. (New) The method of Claim 1 wherein the eye condition is superior limbic keratitis.
- 19
33. (New) The method of Claim 1 wherein the eye condition is pterygium keratitis sicca.
- 20
34. (New) The method of Claim 1 wherein the eye condition is myopia.
- 21
35. (New) The method of Claim 1 wherein the eye condition is Terrien's marginal degeneration.
- 22
36. (New) The method of Claim 1 wherein the eye condition is mariginal keratolysis.

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- (New) The method of Claim 1 wherein the eye condition is radial keratotomy.
- (New) The method of Claim 1 wherein the eye condition is macular degeneration.
- (New) The method of Claim 1 wherein the eye condition is post-laser complications.
- (New) The method of Claim 1 wherein the eye condition is chronic retinal detachment.
- (New) The method of Claim 1 wherein the eye condition is optic pits.
- (New) The method of Claim 1 wherein the eye condition is a hyperviscosity syndrome.
- (New) The method of Claim 1 wherein the eye condition is chronic uveitis.
- (New) The method of Claim 1 wherein the eye condition is chronic vitritis.
- (New) The method of Claim 1 wherein the eye condition is ocular neovascular disease.
- (New) The method of Claim 1 wherein the eye condition is age-related macular degeneration.
- (New) The method of Claim 1 wherein the eye condition is presumed ocular histoplasmosis.
- (New) The method of Claim 1 wherein the eye condition is an infection causing retinitis or choroiditis.
- (New) The method of Claim 1 wherein the eye condition is proliferative vitreoretinopathy.
- (New) The method of Claim 1 wherein the eye condition is scleritis.
- (New) The method of Claim 1 wherein the eye condition is Eales' disease.
- (New) The method of Claim 1 wherein the eye condition is Best's disease.
- (New) The method of Claim 1 wherein the eye condition is trachoma.
- (New) The method of Claim 1 wherein the ulcerative disease is a bacterial ulcer.
- (New) The method of Claim 1 wherein the ulcerative disease is a fungal ulcer.

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56. 40
44 (New) The method of Claim 12 wherein the ulcerative disease is Mooren's ulcer.

57. 40
45 (New) The method of Claim 12 wherein the ulcerative disease is Wegener's sarcoidosis.

58. 40
46 (New) The method of Claim 12 wherein the ulcerative disease is Stevens-Johnson disease.

59. 40
47 (New) The method of Claim 12 wherein the ulcerative disease is Behcet's disease.

60. 40
48 (New) The method of Claim 12 wherein the ulcerative disease is pemphigoid.

61. 40
49 (New) The method of Claim 12 wherein the ulcerative disease is ulcerative colitis.

62. 40
50 (New) The method of Claim 12 wherein the amount administered is between approximately 0.1 and approximately 300 mg/kg/day.

63. 49
51 (New) The method of Claim 62 wherein the amount administered is between approximately 0.5 and approximately 50 mg/kg/day.

64. 50
52 (New) The method of Claim 63 wherein the amount administered is between approximately 1 and approximately 10 mg/kg/day.

65. 40
53 (New) The method of Claim 12 wherein the compound is administered in the form of a tablet or capsule.

66. 40
54 (New) The method of Claim 12 wherein the compound is administered in the form of a lozenge, a cachet, a solution, a suspension, an emulsion, a powder, an aerosol, a suppository, a spray, a pastille, an ointment, a cream, a paste, a foam, a gel, a tampon, or a pessary.

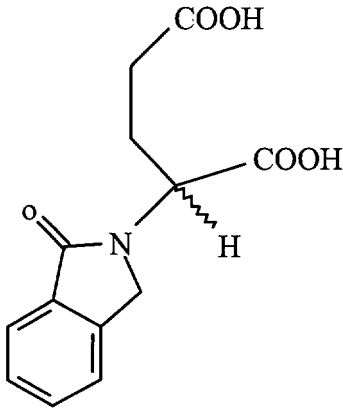
67. 40
55 (New) The method of Claim 12 wherein the administration is oral, parenteral, transdermal, or topical.

68. 40
56 (New) The method of Claim 12 wherein the administration is sublingual, buccal, rectal, vaginal, or nasal.

69. 56
57 (New) The method of Claim 14 wherein the skin condition is acne.

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- 68*
- (New) The method of Claim 80 wherein the condition is trauma.
- 68*
- (New) The method of Claim 80 wherein the condition is sjogren's syndrome.
- 68*
- (New) The method of Claim 80 wherein the condition is phlyectenulosis.
- 68*
- (New) The method of Claim 80 wherein the condition is sarcoid.
- 68*
- (New) The method of Claim 80 wherein the condition is pseudoxanthoma elasticum.
- 68*
- (New) The method of Claim 80 wherein the condition is Stargardt's disease.
- 68*
- (New) The method of Claim 80 wherein the condition is Paget's disease.
- 68*
- (New) The method of Claim 80 wherein the condition is Lyme's disease.
- 68*
- (New) The method of Claim 80 wherein the condition is par planitis
- 68*
- (New) The method of Claim 80 wherein the condition is pyogenic granulomas.
- 68*
- (New) The method of Claim 80 wherein the condition is lipid degeneration.
- 68*
- (New) The method of Claim 80 wherein the condition is Crohn's disease.
- 68*
- (New) The method of Claim 80 wherein the condition is chronic inflammation.

82
94.

(New) The method of Claim ⁶⁸80 wherein the condition is acoustic neuroma.

83
95.

(New) The method of Claim ⁶⁸80 wherein the condition is abnormal proliferation of fibrovascular or fibrous tissue.

84
96.

(New) The method of Claim ⁶⁸80 wherein the amount administered is between approximately 0.1 and approximately 300 mg/kg/day.

85
97.

(New) The method of Claim ⁶⁸90 wherein the amount administered is between approximately 0.5 and approximately 50 mg/kg/day.

86
98.

(New) The method of Claim ⁸⁵97 wherein the amount administered is between approximately 1 and approximately 10 mg/kg/day.

87
99.

(New) The method of Claim ⁶⁸80 wherein the compound is administered in the form of a tablet or capsule.

88
100.

(New) The method of Claim ⁶⁸80 wherein the compound is administered in the form of a lozenge, a cachet, a solution, a suspension, an emulsion, a powder, an aerosol, a suppository, a spray, a pastille, an ointment, a cream, a paste, a foam, a gel, a tampon, or a pessary.

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101.

(New) The method of Claim ⁶⁸80 wherein the administration is oral, parenteral, transdermal, or topical.

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102.

(New) The method of Claim ⁶⁸80 wherein the administration is sublingual, buccal, rectal, vaginal, or nasal.

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REMARKS

Claims 2, 10-11, 13, and 15-22 have been canceled, and Claims 23-102 have been added. No claim has been amended. Therefore, with entry of the present amendment, Claims 1, 3-9, 12, 14, and 23-102 are pending. Support for the new claims can be found in the original claims.

The present amendment is accompanied by a check in the amount of \$612.00 to cover the fee for additional claims for which a fee has not previously been paid. No additional fees are believed due. However, the Commissioner is hereby authorized to charge any deficit or credit any overpayment to Deposit Account No. 11-0855.

PROVISIONAL REJECTION OF CLAIMS 1-22 UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS TYPE DOUBLE PATENTING

Claims 1-22 have been rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-24, 26-58, 63-69, and 76-87 of Application No. 09/788,872. The Office Action states that "although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the application claim[s] are directed to the same disease condition[s]."

Applicant respectfully traverses this rejection for the following reasons. Please note that Claims 1-87 were previously canceled in Application No. 09/788,872. Applicant has responded as if the rejection were over pending Claims 88-132 of Application No. 09/788,872. The overlapping subject matter between the claims of the present application and Application No. 09/788,872 has been delineated by amendment to both applications. The claims of the present application are drawn to methods of treating eye conditions, methods of treating ulcerative diseases, and methods of treating skin conditions. Claims 80-102 are also drawn to the treatment of a number of other diseases. In contrast, the claims of Application No. 09/788,872 have been amended to recite methods of treating a non-tumor blood conditions, methods of treating immune diseases, and methods of treating infections.

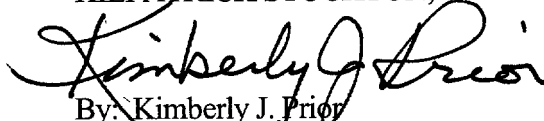
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The Office Required restriction between the diseases now claimed in the two applications in parent application 08/950,673. Therefore, Applicants assert that the claims of the two application are not obvious in view of one another and respectfully requests reconsideration of this ground of rejection.

The foregoing is a complete response to the Office Action issued May 11, 2001. The claims are believed to be allowable. Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 949-2400 is respectfully solicited.

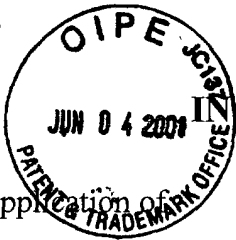
Respectfully submitted,

KILPATRICK STOCKTON, LLP


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Atty Docket: 05213-0650
KS#: 43170-219681





IN THE U.S. PATENT AND TRADEMARK OFFICE

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In re Application of

Docket No. 43170-219681 (05213-0650)

D'Amato

Serial No. 09/545,139

Filed: April 7, 2000

For: Methods and Compositions for Inhibition of Angiogenesis with EM-138

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Transmitted herewith is a paper in the above-identified application.

- ☒ Small entity status of this application under 37 C.F.R. §1.9 and §1.27 has been established by a verified statement.
- ☐ Applicant claims small entity status.
- ☐ No additional fee is required.
- ☒ The additional fee is calculated as shown below:

					SMALL ENTITY		OTHER THAN SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDIT. FEE	RATE	ADDIT. FEE
TOTAL	90	MINUS	22=	68	x9	\$612	x18	\$
INDEP.	4	MINUS	9=	0	x40	\$	x80	\$
<input type="checkbox"/>	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIMS				+135	\$	+270	\$
TOTAL ADDITIONAL FEE					\$612.00		\$	

- ☒ A check in the amount of \$612.00 is attached.
- ☒ The Commissioner is hereby authorized to charge any additional fees required under 37 CFR §1.16, or credit any overpayment, to Account No. 11-0855. A duplicate copy of this sheet is enclosed.

I hereby certify that this correspondence is being deposited with with the United States Postal Service as first class mail in an envelope addressed to. Assistant Commissioner for Patents, Washington, D.C. 20231, on May 30, 2001

Signature

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